

WHAT IS CLAIMED IS:

1. A method for evaluating clinical acceptability of at least one of reference and sensor analyte data, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including one or more reference data points; and

evaluating the clinical acceptability at least one of said reference and sensor analyte data using substantially time corresponding reference or sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data.

2. The method of claim 1, further comprising providing an output through a user interface responsive to said clinical acceptability evaluation.

3. The method of claim 2, wherein the step of providing an output includes alerting the user based on said clinical acceptability evaluation.

4. The method of claim 2, wherein the step of providing an output includes altering the user interface based on said clinical acceptability evaluation.

5. The method of claim 4, wherein the step of altering the user interface includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

6. The method of claim 1, wherein the step of evaluating the clinical acceptability includes using one of a Clarke Error Grid, a mean absolute difference calculation, a rate of change calculation, a consensus grid, and a standard clinical acceptance test.

7. The method of claim 1, further comprising requesting additional reference data if said clinical acceptability evaluation determines clinical unacceptability.

8. The method of claim 7, further comprising repeating the clinical acceptability evaluation step for said additional reference data.

9. The method of claim 1, further comprising a step of matching reference data to substantially time corresponding sensor data to form a matched pair after the clinical acceptability evaluation step.

10. A system for evaluating clinical acceptability of at least one of reference and sensor analyte data, the method comprising:

means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, including one or more reference data points; and

means for evaluating the clinical acceptability of at least one of said reference and sensor analyte data using substantially time corresponding reference and sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data.

11. The system of claim 10, further comprising means for providing an output based through a user interface responsive to said clinical acceptability evaluation.

12. The system of claim 11, wherein said means for providing an output includes means for alerting the user based on said clinical acceptability evaluation.

13. The system of claim 11, wherein said means for providing an output includes means for altering the user interface based on said clinical acceptability evaluation.

14. The system of claim 13, wherein said means for altering the user interface includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

15. The system of claim 10, wherein said means for evaluating the clinical acceptability includes using one of a Clarke Error Grid, a mean absolute difference calculation, a rate of change calculation, a consensus grid, and a standard clinical acceptance test.

16. The system of claim 10, further comprising means for requesting additional reference data if said clinical acceptability evaluation determines clinical unacceptability.

17. The system of claim 16, further comprising means for repeated the clinical acceptability evaluation for said additional reference data.

18. The system of claim 10, further comprising means for matching reference data to substantially time corresponding sensor data to form a matched data pair after the clinical acceptability evaluation.

19. A computer system for evaluating clinical acceptability of at least one of reference and sensor analyte data, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including one or more reference data points; and

a clinical acceptability evaluation module that evaluates at least one of said reference and sensor analyte data using substantially time corresponding reference and sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data.

20. The computer system of claim 19, further comprising an interface control module that controls the user interface based on said clinical acceptability evaluation.

21. The computer system of claim 20, wherein said interface control module alerts the user based on said clinical acceptability evaluation.

22. The computer system of claim 20, wherein said interface control module alters the user interface based on said clinical acceptability evaluation.

23. The computer system of claim 22, wherein said interface control module alters the user interface by providing at least one of providing color-coded information, trend information, directional information, and fail-safe information.

24. The computer system of claim 19, wherein said clinical acceptability evaluation module uses one of a Clarke Error Grid, a mean absolute difference calculation, a

rate of change calculation, a consensus grid, and a standard clinical acceptance test to evaluate clinical acceptability.

25. The computer system of claim 20, wherein said interface control module that requests additional reference data if said clinical acceptability evaluation determines clinical unacceptability.

26. The computer system of claim 25, wherein said interface control module evaluates said additional reference data using clinical acceptability evaluation module.

27. The computer system of claim 19, further comprising a data matching module that matches clinically acceptable reference data to substantially time corresponding clinically acceptable sensor data to form a matched pair.

28. A method for evaluating clinical acceptability of at least one of reference and sensor analyte data, the method comprising:

- receiving a data stream from an analyte sensor, including one or more sensor data points;

- receiving reference data from a reference analyte monitor, including one or more reference data points;

- evaluating the clinical acceptability at least one of said reference and sensor analyte data using substantially time corresponding reference and sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data; and

- providing an output through a user interface responsive to said clinical acceptability evaluation.

29. A method for evaluating clinical acceptability of at least one of reference and sensor analyte data, the method comprising:

- receiving a data stream from an analyte sensor, including one or more sensor data points;

- receiving reference data from a reference analyte monitor, including one or more reference data points; and

evaluating the clinical acceptability at least one of said reference and sensor analyte data using substantially time corresponding reference and sensor data, including using one of a Clarke Error Grid, a mean absolute difference calculation, a rate of change calculation, and a consensus grid.

30. A computer system for evaluating clinical acceptability of at least one of reference and sensor analyte data, the computer system comprising:

- a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

- a reference input module that receives reference data from a reference analyte monitor, including one or more reference data points;

- a clinical module that evaluates at least one of said reference and sensor analyte data using substantially time corresponding reference and sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data; and

- an interface control module that controls the user interface based on said clinical acceptability evaluation.

31. A computer system for evaluating clinical acceptability of at least one of reference and sensor analyte data, the computer system comprising:

- a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

- a reference input module that receives reference data from a reference analyte monitor, including one or more reference data points; and

- a clinical module that evaluates at least one of said reference and sensor analyte data with substantially time corresponding reference and sensor data, wherein said clinical module uses one of a Clarke Error Grid, a mean absolute difference calculation, a rate of change calculation, a consensus grid, and a standard clinical acceptance test to evaluate clinical acceptability.

32. A computer system for evaluating clinical acceptability of at least one of reference and sensor analyte data, the computer system comprising:

- a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor via a receiver;

- a reference input module that receives reference data from a reference analyte monitor, including one or more reference data points; and

- a clinical module that uses a Clarke Error Grid to evaluate the clinical acceptability at least one of said reference and sensor analyte data using substantially time corresponding reference and sensor data; and

- a fail-safe module that controls the user interface responsive to the clinical module evaluating clinical unacceptability.

33. A method for evaluating clinical acceptability of at least one of reference and sensor glucose data, the method comprising:

- receiving a data stream from an analyte sensor, including one or more sensor data points;

- receiving reference data from a reference glucose monitor, including one or more reference data points;

- evaluating the clinical acceptability at least one of said reference and sensor glucose data using substantially time corresponding reference and sensor data, wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data; and

- a fail-safe module that controls the user interface responsive to the clinical module evaluating clinical unacceptability.